King County Board of Health

Secure Medicine Return

DRAFT MINUTES

December 5, 2012
9:00 AM – 11:00 AM

Location: King County Courthouse, 12th Floor, Southwest Conference Room

Sub Committee Members: Chair Joe McDermott, Board of Health members David Baker, Richard Conlin, Dr. Bud Nicola, and Public Health Director Dr. David Fleming

Staff: Doreen Booth, SCA; Anne Burkland, CM Joe McDermott's office; Robin Fox, PAO; Jennifer Muhm, Public Health; Erik Sund, KC Council; Maria Wood, BOH Administrator

Observers: Helen St. John, League of Women Voters; Suellen Mele, Zero Waste Washington; Rudy Garza, Coalition for Drug-Free Youth/Navos; Michael Transue, Novo Nordisk; Jeff Gombosky, PhRMA; Scott Sigmon, Consumer Health Products Association; Cliff Webster, PhRMA; Heather Trim, Sierra Club; Lisa Hart, WSNA/KCNA; James Matteacci, Merck; Brad Tower, Genetech; Dave Mastin, Mylan

Time	Agenda Item
9:00	Introductions – Chair McDermott
9:05	Follow up from last meeting Chair McDermott pointed to the draft minutes from the Nov. 14 meeting under "Defining Covered Drugs" and confirmed that committee members decided to accept the proposed exemptions. Dr. Fleming requested that the rationale be edited. These changes will be made in the Nov. 14 minutes.
9:15	Policy discussion – Chair McDermott, staff • Defining the collection system (cont. from last meeting) 2. Define the "convenience standard" to establish the requirement for number and geographic locations of collection options (as selected in 1) that must be provided by the product stewardship program. <u>Discussion</u>: Ms. Shield reviewed various components of a "convenience standard". Dr. Fleming proposed that all pharmacies that want to participate should be allowed to, and if that does not provide enough access, implement a backup plan to expand access. Boardmember Conlin suggested considering population and geography to develop a standard similar to that used in the Washington State bill language; also may consider distance or

travel time to a take back location as part of the standard. In an effort to make the system simple and effective, alternative collection methods (take-back events, mail in, other) should only be implemented if the convenience standard is not met. (What else was decided here? Did they direct staff to figure it out?)

3. Requirement for collection procedures to be used by the product stewardship program.
Discussion: Concepts of simple and effective came up again as guiding principles for designing the system. Importance of protocols/standards was underscored. Don't want to require counting pills, but suggested that periodic sampling or audits might be useful to determine what drugs are being disposed. Chair McDermott suggested that the regulation encourage separating pills from packaging when feasible, but that this not be required.

Decisions:
Dr. Nicola suggested that DEA and Washington State Board of Pharmacy protocols be used as the standard approach. (Was this the decision?)

- Defining how drug producers work together

1.Defining how drug producers work together to provide the medicine take-back program.

Discussion: Ms. Shield reviewed the options. The group focused in on Option C (see Staff Report) including developing standards for approval to "opt out" including assessing the impact of the "opt out" on the system as a whole.

Decisions: Require all producers to participate in a single default or standard plan, unless they "opt out" to form an independent plan. Any independent plan is required to collect all drugs, not just those from a single company.

Rationale: Focused on convenience to the customer, should look like one coherent system from the customer's point of view.

2. Whether to define how drug products apportion program costs

Discussion: Ms. Shield talked through the options and pointed to policy examples from other jurisdictions. Members did not reach a decision and requested staff to propose options for consideration at next meeting. A couple of concepts offered: give producers a timeframe to determine a method for apportioning costs and if they cannot reach a conclusion the department will dictate the method; create an appeals process to be run by the department if one or more producers claims the cost methodology is unfair.

Decision: None reached. Staff directed to develop an approach that can be discussed further. Goal is a simple plan.

- Definition of producers

Discussion: Try to keep this simple. Dr. Fleming suggested a sequenced or tiered approach similar to the producer definition from the B.C. Recycling Regulation in the background materials. Start with producers and involve other entities involved in the retail sale and distribution of pharmaceuticals in the absence of being able to identify a producer. Could include store brand owners if a producer cannot be identified. (did I get that right?)

Decision: Back to staff for options? Can't find the decision articulated in my notes on this one.

Exclusions:
Producer does not include pharmacist compounding drugs to be dispensed from the pharmacy in which the drugs are compounded pursuant to prescriptions for individual patients.

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- Defining costs that drug producers are responsible for

Discussion/Decision:

Cost Category	Costs drug producers are responsible for	Costs that other stakeholders are responsible for
1. Collection	Secure collection boxes, any special packaging, pre-paid mailers	"in kind" staff time at collection site
2. Transportation to Interim Storage at Central Ware house	Yes	
3. Transportation & Final Disposal	Yes	
4. Programmatic	Yes, includes administration, promotion, outreach, evaluation	Collectors and other stakeholders may provide additional promotion and outreach and education
5. Agency Oversight & Enforcement	Needs more discussion as model is determined	

	6. Other?	Nothing added	
10:50	Next steps • Subcommittee requested staff to begin draft rule and regulation incorporating decisions that have been made so far • Subcommittee requested email updates as staff has follow up information • Provide update on subcommittee activity at January 17, 2012 Policies to be considered at the next meeting: • Finish defining costs that drug producers are responsible for • Defining education and program promotion requirements • Definition of "Covered Entitites" • Determining enforcement actions and penalties		
11:00	Adjourn Next meeting: February 1, 2012, 9AM – 1PM, location TBD		